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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/297,877	06/28/1999	VIRGINIA M.-Y. LEE	PENN-0583	1398

7590 10/16/2003

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EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/297,877	LEE ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: 4.

   Claim(s) withdrawn from consideration: _____.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The basis for this rejection is set forth at pg 2-7 of the previous Office Action (16 June 2003).

Applicant asserts that the Examiner has misinterpreted claim 4 and that claim 4 is directed to a method of inhibiting a biological endpoint (i.e., processing of amyloid precursor protein into amyloid beta peptides) which is asociated with one sign (i.e, neuritic plaques and vascular deposits) of Alzheimer's disease and not a method of preventing or treating Alzheimer's disease. It is noted to Applicant that the Examiner has not misinterpreted claim 4 as prevention or treatment of Alzheimer's disease. Applicant asserts that an in vitro model example which correlates with the disclosed or claimed method of invention has been provided. Applicant contends that the assertion that the claimed invention is useful in inhibiting a sign of a disease in a patient would be considered credible and predictable by a person of ordinary skill in the art on the basis of using the NTN2 cells to identify an agent which modulates the levels of amyloid beta peptides formed in the ER of said cells. Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, no substantially new arguments regarding this issue have been presented, and thus the rejections are maintained for reasons of record. Applicant also asserts that as the secretase enzymes are proteases, the skilled artisan would know of, e.g. protease inhibitors or classes of other compounds which may be identified by contacting NT2N cells with such classes of agents and measuring levels of amyloid beta peptides formed in the ER of said cells. Applicant also indicates that the courts have recognized that while a specification may lack examples of specific dosages, the application is considered enabled to one skilled in the art if the agent has certain pharmacological properties. Applicant's arguments have been fully considered but are not found to be persuasive. Since the specification provides no guidance regarding what sort of agents should be screened for inhibiting the processing of amyloid precursor protein, the skilled artisan must resort to trial and error experimentation to determine which class of compounds might yield one with the desired activity. Such trial and error experimentation is considered undue. The skilled artisan must also resort to trial and error experimentation to determine the optimal dosage, duration, and mode of administration of all possible agents. According to MPEP § 2164.06, "the guidance and ease in carrying out an assay to achieve the claimed objectives may be an issue to be considered in determining the quantity of experimentation needed." Finally, Applicant asserts that the skilled artisan, upon reading Brinton et al. and Roses et al., would have little understanding of the state of the art or the predictability of inhibiting the processing of amyloid precursor protein into amloid beta peptides found in neuritic plaques and vascular deposits that accumulate in the brains of patients with Alzheimer's disease. Applicant's arguments have been fully considered but are not found to be persuasive. The first step of claim 4 is identifying an agent that decreases the processing of amyloid precursor protein into amyloid beta peptides and the second is step is actually administering this agent to patients with Alzheimer's disease (AD) to inhibit the processing of amyloid precursor protein into amyloid b peptides found in neuritic plaques and vascular deposits that accumulate in the brain. Therefore, claim 4 reads upon administering an agent to an AD patient. Brinton et al. and Roses are pertinent references since they comment on the status of AD treatment at the time the application was filed. Although neither reference discusses inhibition of the processing of amyloid precursor protein into amloid beta peptides in vivo, they indicate examples of challenges that may be encountered when administering a possible therapeutic drug to a patient with Alzheimer's disease.